K001907

SEP - 5 2000

Camit Diabetes Management Software

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 845-2000

Contact Person: Mike Flis

Date Prepared: June 9, 2000

2) Device name

Proprietary name: Camit Diabetes Management Software
Common name: diabetes management software
Classification name: calculator/data processing module for clinical use
Classification regulations: 862.1345 and 862.2100

3) Predicate device

We claim substantial equivalence to the Lifescan IN TOUCH Diabetes Management Software.

4) Device Description

The Camit Diabetes Management Software is an optional software accessory for use with Roche blood glucose monitors with data management capabilities such as Accu-Chek Advantage and Accu-Chek Complete Meters. When used with one of these meters, Camit permits the transfer of data from the glucose meter memory into a computer for enhanced data management capability.

Continued on next page

510(k) Summary, Continued

5) Intended use

The Camit Diabetes Management Software is intended for use in home and clinical settings to aid people with diabetes and their health care professionals in review, analysis and evaluation of historical blood glucose test results to support effective diabetes management.

6) Comparison to predicate device

The Roche Camit Diabetes Management Software is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Lifescan IN TOUCH Diabetes Management Software. The Lifescan product received its clearance determination on April 29, 1999 [#k984527].

Both software programs can be described as follows:

- an optional software accessory for use with blood glucose monitors with data management capabilities
- intended for use in home and clinical settings to aid people with diabetes and their health care professionals in review, analysis and evaluation of historical blood glucose test results to support effective diabetes management
- do not in any way control or affect the blood glucose monitors' measurements

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 8 2000

Mr. Mike Flis
Regulatory Affairs Principal
Roche Diagnostics Corporation
9115 Hague Road
PO Box 50457
Indianapolis, Indiana 46250-0457

Re: K001907
Trade name: Camit Diabetes Management Software
Regulatory Class: II
Product Code: CGA
Regulatory Class: I
Product Code: JQP
Dated: August 25, 2000
Received: August 28, 2000

Dear Mr. Flis:

This letter corrects our substantially equivalent letter dated September 5, 2000, regarding the indications for use.

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K001907
Device Name: Camit Diabetes Management Software

Indications for Use:

The Camit Diabetes Management Software is an optional software accessory for use with Roche blood glucose monitors with data management capabilities such as Accu-Chek Advantage and Accu-Chek Complete Meters. When used with one of these meters, Camit permits the transfer of data from the glucose meter memory into a computer for enhanced data management capability.

The Camit Diabetes Management Softwae is intended for use in home and clinical settings to aid people with diabetes and their health care professionals in review, analysis and evaluation of historical blood glucose test results to support effective diabetes management.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K001907

Prescription Use ✓ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)